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PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,016	HIRSH ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination 1/23/06 is acknowledged. Claims **33-57** are pending in this application. Claims 1-32 stand cancelled.

Claim Rejections - 35 USC § 112

The rejection of claims 41, 51, and 54 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's arguments pointing to support.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 33 and independent claim 55 is directed to a second oral portion which is released for uptake in the intestine and wherein the second portion is either a sustained release or chewable formulation. It is unclear how the second oral portion is released in the intestine and yet is capable of being chewed. The examiner points out that the claim is directed to a sustained release or chewable formulation. If the composition is chewed then it cannot be released in the intestine as required by the claim. Further clarification is requested.

Claim 1, 41, and 55 respectively recite the limitation "the core". There is insufficient antecedent basis for this limitation in the claim.

Claim 37 recites the limitation "comprises one or more of the outer layers". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33-39, 41-50, and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 800,973 in view of Powell et al (6,140,319) in further view of DE 3338978 in further view of Fennel et al (3,898,323).

GB teaches a multi-layered tablet comprising 1) an outer coating that contains a medicament that readily dissolves in the mouth 2) a signal layer containing a distinctive flavor, 3) an enteric layer around an inner layer comprising an oral medicament, and 4) a core that can also contain a medicament. See figure1 and claim 1 and 3. The outer coat is taught to readily dissolvable in the mouth. See column 2, lines 59-65. GB discloses that the enteric layer may be manipulated with a certain thickness to release the medicament in a given area or time, which is

known in the art. See page 2. GB teaches that the tablet provides a means for dosing a patient with at least two separate medicaments, one of which is to be absorbed in the mouth and the other in the gastro-intestinal tract. See column 2, lines 47-59.

Example 1 teaches the immediate drug on the outside as N-isopropylarterenol and the delayed core is theophyllin. Example 2 teaches an inner core is coated with three coats of shellac and then an alarm layer is coated over this. The immediate layer comprising 10% nitroglycerin (molecular weight of 227.09) is dusted. The tablet is utilized to promptly treat angina followed by the delayed action of pentaerithrytol in the inner core. Optionally the outer medicament layer may comprise the flavor components of the alarm layer. Note it is the examiner's position that the medicament core reads on chewable formulation since chewable does not impart any structure except that it must be capable of being chewed.

GB does not teach instant drugs as defined in independent claim.

Powell teaches vasopeptidase inhibitors to treat angina pectoris. Powell teaches the vasopeptidase inhibitor in combination with other active agents known to treat angina. These agents include nitroglycerin, instant verapamil hydrochloride, instant amlodipine, etc. See column 4, lines 5-15.

DE teaches the use of verapamil (taught as a cardiovascular agent) in the amount of 5-25mg in a sublingual or buccal tablet. See abstract.

Fennel teaches the process of a coating a core by tumbling the core in a drum containing the coating material or spray coating. Fennel teaches alternatively the coating may be applied over the tablet core by compressing the core with a tablet press. See column 3, lines 14-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings of Powell and utilize the instant verapamil in GB's nitroglycerin example. One would have been motivated to do so since Powell teaches that the prior art's nitroglycerin and instantly claimed drug verapamil are both utilized to treat angina. Thus, a skilled artisan would have been motivated to substitute nitroglycerin with verapamil with the expectation of similar results since GB teaches the use of nitroglycerin to promptly treat angina and the prior art teaches that both drugs treat angina.

Further, one would have been motivated to look to DE and utilize the instant amount of verapamil since the prior art teaches an amount of 5-25 mg is utilized in a sublingual/buccal tablet. Additionally, a skilled artisan would have expected success in utilizing verapamil in GB's dosage form since GB teaches the only criticality of the medicament in the first layer is that it must be capable of being absorbed in the mouth and DE demonstrates verapamil satisfies this requirement; i.e. it is capable of being absorbed buccally or sublingually.

With regard to the recitation that the coating is applied as a film coating or as a compression coating, the examiner points out that application of the coating by compressing it around the core is a product by process limitation. Thus, regardless of the process in which the coating is applied, the product yielded is the same. However, the examiner relies on Fennel to teach various coating methods. Fennel teaches tablets may be coated in various ways including instantly claimed compression coating and tumble coating as taught by GB. Thus, a skilled artisan would have expected results by utilizing a coating compression rather than the method taught by GB since Fennel teaches both manners are conventionally known and utilized for coating cores.

Note that it is the examiner's position that the prior art's readily dissolvable outer layer will implicitly have the dissolving time of claim 48 since the immediate layer is structurally similar to the instantly claimed intraoral layer.

With regard to claim 46, the examiner cites US 6,228,396 wherein the references states that a coating such as shellac provides for a breakup in about 3-4 hours. See column 3, lines 9-25.

Response to Arguments

Applicant argues that GB '973 (Sterling) does not teach the first intraoral portion, which rapidly dissolves or disintegrates intraorally for buccal or sublingual absorption, comprising the instant active agent. Applicant argues Powell and DE (Fromme) does not disclose or suggest a composition comprising a first intraoral portion, which rapidly dissolves or disintegrates intraorally to release the a medicament thorough the buccal or sublingual mucosa and a second component that is chewable or provides sustained release. Applicant argues that one feature of the instant invention is low molecular weight drugs. Applicant argues that Powell does not disclose a relationship between molecular weight and/or structural features and the uptake in the oral cavity. Applicant argues that Powell teaches a combination of the instant drug with omapatrilat which has a molecular weigh to of 408.5.

Applicant's arguments filed 1/23/06 have been fully considered but they are not persuasive. Firstly, the examiner notes that Sterling does not teach the instant active agents; hence the rejection is made under obviousness and not anticipation. Also, the examiner points out that independent claim 41 only requires a drug with a molecular weight of less than 350 daltons and thus Sterling's nitroglycerin reads on this. Sterling teaches a tablet comprising (1) an

outer coating containing a medicament that readily dissolves in the mouth, which reads on applicant's intraoral portion (2) a signal layer containing a distinctive flavor, which reads on claim 41 middle layer) and (3) an enteric layer around an oral medicament inner layer or core to be swallowed, which reads on applicant second portion. Sterling teaches the use of nitroglycerin in the intraoral portion and although nitroglycerin is not part of the instantly claimed Markush group of independent claim 3 and 55, it is capable of being absorbed buccally/sublingually. The examiner points out that page 10 of the instant specification clearly states that nitroglycerin is capable of being taken thorough the oral mucosa. The examiner further cites Remington's Pharmaceutical Sciences, Eighteenth Edition, page 844 that clearly discloses nitroglycerin for sublingual and buccal routes are known. Thus, the only teaching lacking with regard to independent claim 33 and 55 is the instant drugs since Sterling clearly discloses the instant inventive thrust. Note column 2, lines 47-55 wherein Sterling discloses "The present invention provides a means for dosing a patient with at least two separate medicaments, one of which is to be absorbed in the mouth and the other in the gastro-intestinal tract". It is the examiner's position from this disclosure alone that any drug that meets Sterling's criticality for the first portion and second portion may be used, i.e. the first portion must have a drug that can be absorbed in the mouth.

Thus, the examiner relies on the secondary reference to teach the functional equivalence of the instant verapamil and amlodipine with the prior art's nitroglycerin. Powell teaches amlodipine, verapamil, and nitroglycerin all function to treat angina (see column 4, lines 5-16) and the pharmaceutical forms includes buccal and sublingual (see column 3, lines 60-65). Moreover, Fromme clearly teaches a verapamil buccal and sublingual tablet. Hence, meeting the

requirement set forth by Sterling for the drug in the first portion. Applicant has not even addressed this motivation, rather applicant attacks the references individually. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With regard to Powell not recognizing the relationship between molecular weight and its uptake in the oral cavity. It is firstly pointed out that the features upon which applicant relies are not recited in the rejected claims 33-39, 42-50, 52-53, and 55-57. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, applicant's purported inventive concept of only utilizing certain molecular weight drugs is not even claimed. Moreover, the majority of the drugs claimed in independent claim 33 and 55 have a molecular weight over 350 daltons.

With regard to Powell and Fromme not teaching the instant first intraoral portion and second oral portion and further teachings other active agents with a high molecular weight, the examiner points out that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the primary reference, Sterling is not deficient in the teaching of a first intraoral potion and a second oral portion since Sterling clearly teaches this. The examiner's motivation to look to the

secondary references is based on functional equivalency wherein the prior art clearly teaches that nitroglycerin and instant verapamil and amlodipine all function to treat angina and can be formulated into a buccal/sublingual form. Moreover, the motivation to use the instant drug versus the prior art's nitroglycerin is that the prior art (Fromme) teaches verapamil can also be used to treat cardiovascular disorders with a sublingual or buccal tablet.

Applicant argues that enteric is different from sustained release and thus Sterling fails to disclose a second component that is chewable or provides sustained release. The examiner acknowledges the difference between enteric release and sustained. However, it is pointed out that the claim also recites "sustained releases or chewable formulation". It is the examiner's position that Sterling reads on this since "chewable formulation" is intended use without imparting any structural feature. Thus, Sterling's core is capable of being chewed and thus reads on the instant invention. The examiner suggests specifying the chewing formulation comprises a gum base which would overcome the examiner's interpretation of the instant phrase.

Claims 41, 51, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 800,973 in view of Remington's Pharmaceutical Sciences, Eighteenth Edition (1990), page 844 optionally in further view of Fennel et al (3,898,323).

GB teaches a multi-layered tablet comprising 1) the outer coating contains a medicament that readily dissolves in the mouth 2) a signal layer containing a distinctive flavor between the outer coating and core and 3) an enteric layer around an oral medicament core to be swallowed. See figures and column 2 in its entirety. The outer coat is taught to readily dissolve in the mouth. See column 2, lines 59-65. GB discloses that the enteric layer may be manipulated with a certain thickness to release the medicament in a given area or time, which is known in the art. See page

2. GB discloses that the tablet provides a means for dosing a patient with at least two separate medicaments, one of which is to be absorbed in the mouth and the other in the gastro-intestinal tract. See column 2, lines 47-59. Note that "enteric coating" provides release in the intestine.

Example 1 teaches the immediate drug on the outside as N-isopropylarterenol and the delayed core is theophyllin. Example 2 teaches the immediate layer-containing nitroglycerin to promptly treat angina followed by the delayed action of pentaerithrytol in the inner core. The inner core is coated with three coats of shellac and then an alarm layer is coated over this. Thereafter, the tablet is coated with a therapeutic dose of nitroglycerin (10%) for prompt relief. Note that nitroglycerin has a molecular weight of 227.09.

Although GB teaches using nitroglycerin in an amount of 10% for the outer coating, GB does not teach the nitroglycerin dosage in instant terms, i.e. instant 0.001mg to 50mg.

Remington's Pharmaceutical Sciences discloses that nitroglycerin has a molecular weight of 227.09 and that dose nitroglycerin is used. The reference teaches for buccal tablets 1mg is used and for sublingual tablets for an acute attack 0.15-0.6mg is used. See page 844.

Fennel teaches the process of a coating a core by tumbling the core in a drum containing the coating material or spray coating. Fennel teaches alternatively the coating may be applied over the tablet core by compressing the core with a tablet press. See column 3, lines 14-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the teachings Remington's Pharmaceutical Sciences and utilize the instant amount of nitroglycerin. One would have been motivated to do so since Remington's teaches the instant concentration of nitroglycerin that is routinely used to treat angina. Further, Remington teaches the use of 0.15-0.6 mg for an acute attack and GB teaches the use of the outer layer of

nitroglycerin for prompt relief of angina. Lastly, it should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The recitation that the coating is applied as a film coating or as a compression coating is a product by process limitation and regardless of the process in which the coating is applied, the product would be the same. However, the examiner relies on Fennel to teach various coating methods. Fennel teaches tablets may be coated in various ways including instantly claimed compression coating and tumble coating as taught by GB. Thus, a skilled artisan would have expected results by utilizing a coating compression rather than the method taught by GB since Fennel teaches both manners are conventionally known and utilized.

Response to Arguments

Applicant argues that Sterling does not teach an effervescent agent or a signaling system located between the intraoral and oral component. Applicant argues that Sterling does not teach film coating or a compression coating.

Applicant's arguments filed 1/23/ have been fully considered but they are not persuasive. The examiner points to the Figures and example wherein the alarm layer is between the core and outer medicament layer. With regard to the application of the coating, the examiner points out that this a product-by-process limitation. MPEP section 2113 states "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product

of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). However, the examiner has also relied on Fennel to teach various coating methods.

Claims 33-36, 38-39, 43-44, 47-49, 52-53, and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neuser et al (PGPUB 2001/0002999) in view Lewis et al (4,661,492) in further view of Liedtke (5,686,122).

Neuser teaches an analgesic combination wherein the core of the tablet contains a systemically acting analgesic and the outer coating contains a locally acting analgesic/anaesthetic. The locally acting analgesic has a rapid onset and the systemic portion has a sustained action for a duration of at least 3 hours. See claim 1 and paragraph 0015. The local analgesic is a drug that has an onset action of one minute and particularly 30 seconds and is utilized in an amount of 2-30mg. See paragraph 0007. The local analgesic is selected from lidocaine (234.34), prilocaine (256.77), mepivacaine, procaine (272.77), etc., with a preference for benzocaine (165.19). See paragraph 0009 and 0014. Neuser teaches preparing the formula by press coating (compression coating). Neuser teaches a core comprising naproxen, microcrystalline cellulose, and orange flavor is coated with a coating syrup comprising lidocaine. See examples.

Neuser does not teach the instant drugs claimed.

Lewis et al teach an analgesic composition that may be in the form of a sublingual or parenteral form. The analgesic, buprenorphine, is included in the therapeutic amount of 0.1 mg to 0.4mg sublingually for the treatment of pain. See column 2, lines 61-66.

Liedtke teaches local anaesthetics including buprenorphine, lidocaine, prilocaine, and mepivacaine. See column 3, lines 1-10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Neuser et al and Lewis et al and substitute Neuser's anaesthetics with the instantly claimed drug buprenorphine in the instant amount. One would have been motivated to do so since Lewis et al teach the analgesic effects of buprenorphine in a sublingual tablet form. Further, Liedtke teaches the anaesthetics taught by Neuser et al and instant buprenorphine function as local anesthetics. Thus, a skilled artisan would have expected similar results and success by substituting the prior art's anaesthetic with buprenorphine since the prior art establishes the functional equivalency.

With regard to claim 47, it is the examiner's position that the recitation "wherein the second oral portion is chewable and comprises at least one pharmaceutically acceptable excipient suitable for chewable medication" is intended use. Further, if the prior art structure is capable of performing the said intended use, then it meets the intended use. In the instant case, Neuser's GI portion is capable of being chewed and the excipients used in the core are also capable of being chewed, thus it meets the claim limitation.

Claims 33-36, 38-40, 42-44, 47-48, 52-53, 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/35296 to Johnson.

Johnson teaches a composition and method of making a chewing gum wherein an active agent is contained in the gum core and in the coating. The active in the coating agent may be further mixed with a flavor. See abstract. Johnson teaches the medicament in the coating provides a quick release of the active into the saliva. After chewing the gum, the pressure within

the buccal cavity forces the active into the systemic system. See page 4. Johnson teaches the gum coating containing a medicament will have a fast release whereas the core containing a medicament may be encapsulated for a slow release. See page 15. Johnson teaches a chewing time proving slow release for 40 minutes. See page 8.

Johnson teaches a variety of medicament including the instantly claimed buspirone disclosed as an antidepressant and verapamil disclosed as a cardiovascular drug. See page 11-12. The medicaments are provided in an amount of 12 micrograms to 250 milligrams. See page 13.

The chewing gum portion contains a gum base and flavoring agent. See page 17. The gum coating contains flavoring agents, cellulose polymers, antitack agents (glidants), colorants, plasticizers, etc.. See page 22-23 and page 24 (last paragraph).

Johnson does not exemplify the instantly claimed active agents.

However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to utilize the instant drugs buspirone or verapamil. One would have been motivated to utilize the buspirone or verapamil with the expectation of similar results since Johnson suggests this. Further, the selection of a particular drug is dependent on the desired treatment. Thus, for instance, if a skilled artisan desired treat angina, one would have been motivated to utilize a cardiovascular drug such as verapamil.

With regard to claims 35-36, note that the definition of a tablet is a small pellet to be taken orally; thus Johnson reads on this limitation. Also on page 17, Johnson teaches "tableting" the chewing gum. The definition of a capsule is a small soluble container enclosing an oral medication.

Note that it is the examiner's position that the prior art's readily dissolvable outer layer will implicitly have the dissolving time of claim 48 since the immediate layer is structurally similar to the instantly claimed intraoral layer.

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/35296 to Johnson in view of Jao et al (5,310,561).

The teachings of Johnson have been set forth above. Johnson teaches a variety of medicaments depending on the desired treatment.

Johnson does not teach the use of ondansetron (325 daltons).

Jao teaches the administering ondanestron in an amount of 1mg to 400mg to the buccal mucosa for the treatment of nausea. See claim 4.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to utilize ondansetron in Johnson's gum coating. One would have been motivated to do so if one wanted to treat nausea. Further, one would have expected success since Johnson teaches the gum coating contains an active that administers the drug to the buccal mucosa.

Claims 33-43 and 49-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al (5,053,032) in view of Panther et al (6,200,604).

Barclay et al disclose an osmotic device for delivering a beneficial agent. Barclay's tablet houses two regions, one for delivering a predetermined dosage via buccal administration of a drug and a second region for delivering the remainder of the dose to the GI tract (Note abstract, col. 8, lines 28-51). Further, the tablet contains a signaling in the form of a flavoring agent or coloring agent that alerts the patient that the buccal administration dosage has been delivered and the remainder may be swallowed (col. 3, lines 57-68, col. 5, lines 25-55). In a preferred

embodiment the first active agent has a first flavor and the hydrophilic polymer layer containing the second portion contains a second flavoring agent. See column 5, lines 25-55. The reference discloses several drugs including instant drug prochlorperazine, nitroglycerine (227.09), ibuprofen (206.28), naproxen (230.26), levodopa (197.19), etc. that are suitable for the delivery device on column 10, line 50 to column 11, line 35. The drug is used in an amount of 0.05ng to 500 mg. See column 12, lines 23. Barclay discloses the process of making the device and compression of the layers (example 1). Osmagents such as sodium carbonate are taught in the osmotic device. See column 12 lines 27-45 and example 3. The device delivers the active agent over an extended period of time, i.e. 0.5-12 hours. See column 15, lines 15-20.

Example 3 discloses an oral osmotic device wherein the inner core contains 20.5 ibuprofen, 66.5% polyox, 5% HPMC, 7.5% sodium carbonate, and 0.5% magnesium stearate. This core is coated with a layer containing 20% ibuprofen (206.28 molecular weight), and 80% HPMC (cellulose). The overcoat layer is completely removed within about 15 minutes to 30 minutes. Further, the device contains a color-coding signaling system.

Although, Barclay teaches the instant drug prochlorperazine of independent claim 33, Barclay does not exemplify it and its dosage amount.

Panther teaches a sublingual buccal effervescent which contains an orally administrable drug in combination with an effervescent to promote the absorption of the medicament in the oral cavity. See abstract. Panther teaches the use of the effervescent as a penetration enhancer to influence the permeability of the medicament across the oral mucosa. See column 2, lines 5-11. Panther also teaches the prior art use of effervescent agents in buccal administered dosage forms to mask the taste of the medicament. See column 1, lines 30-40. Lastly, Panther teaches the use

of a variety of medicaments in the sublingual formula. Panther exemplifies the use of prochlorperazine in the amount of 5 mg. See example 2. Lastly, Panther teaches the use of a variety of medicaments including the ones disclosed in US patent 5,234,957. US '957 discloses of drugs such as ibuprofen.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Barclay et al and Panther and utilize an effervescent agent in the buccal region of Barclay's device. One would have been motivated to do so since Panther teaches the use of effervescent agents as penetration enhancers in sublingual/buccal tablets, which facilitates the permeation of the drug across the oral mucosa. Therefore, a skilled artisan would have been motivated to add an effervescent agent to increase the penetration of the drug through the oral mucosa. Moreover, Panther teaches the instant amount of the instant prochlorperazine utilized in the formulation. Therefore, the instant invention is prima facie obvious.

With regard to claim 47, it is the examiner's position that the recitation "wherein the second oral portion is chewable and comprises at least one pharmaceutically acceptable excipient suitable for chewable medication" is intended use. Further, if the prior art structure is capable of performing the said intended use, then it meets the intended use. In the instant case, Barclay's GI portion is capable of being chewed and the excipients used in the core are also capable of being chewed, thus it meets the claim limitation.

Response to Arguments

Applicant argues that Barclay teaches an osmotic device. Applicant argues that the device cannot be used to deliver two different drugs. Applicant argues that Barclay does not teach a sustained release or a chewable formulation.

Applicant's arguments filed 1/23/06 have been fully considered but they are not persuasive. The examiner points out that the rejected claims do not recite or require two different drugs in the device. Additionally applicant argues that Barclay makes not distinction between the drugs used and the molecular weight. The examiner points out that independent claim 33 and 55 do not recite any limitation with regard to the molecular weight. It is noted that applicant has repeatedly stated this is the novel feature of the instant invention; however applicant does not claim this purportedly distinguishing feature.

Applicant argues that Barclay teaches an osmotic device and thus one would not be motivated to chew a osmotic device. The examiner points out that the recitation of "chewable formulation" does not limit the composition since the term chewable is intended use and does not impart a structural limitation. Therefore, the patentability lies with the product/composition and not the use of the product after administration. Thus, regardless if one would have been motivated to chew the Barclay's core or not, it is clearly capable of being chewed and thus meets the intended use limitation. Moreover, the examiner points out that although applicant repeatedly argues the instant claims are not directed to an osmotic device, applicant's claim language does not exclude a osmotic device. Also note the 112, second paragraph rejection.

Applicant argues that Barclay teaches away from a sustained release portion. This argument is perplexing since clearly Barclay teaches hydroxypropylmethylcellulose (HPMC) in

the core of the device and this polymer is recognized in the art to impart a sustained release. HPMC is also taught as a sustained release polymer by applicant on page 25, line 2 of the instant specification.

Applicant argues that the first oral portion disintegrates or dissolves within 10 minutes as claimed in dependent claim 48 and Barclay teaches a release of 0.5-12 hours. Firstly, the examiner points out that claim 48 is not rejected and thus applicant's argument is moot. Additionally, the examiner points out that applicant incorrectly characterized Barclay. Example 3 of Barclay teaches the outer layer (akin to instant first portion) is removed within about 15 minutes to 30 minutes.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of US 6863901 and 1-20 of 11/041474. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications contain similar subject matter is maintained.

Instant application claims a composition and a process of preparation with an intraoral portion for sublingual or buccal administration, specific drugs, drug amount, and a second oral portion to be released in the GI tract. Claim 35 recites the composition in a tablet or capsule form. Claims 38-39 claims a film coating. Claim 41 claims an effervescent agent in the outer coating. Claim 43 recites a sustained release formulation. Claims 44 and 46 claim a release rate of 0.5-24 hours. Claim 48 claims the outer layer dissolves within 10 minutes.

US '901 claims a composition and a process of preparation with an intraoral portion for sublingual or buccal administration and a second oral portion to be released in the GI tract. Claim 2 recites the composition in a tablet or compressed tablet form. Claim 6 claims a film coating. Claim 5 claims an effervescent agent in the outer coating. Claim 8 and 10 recite a sustained release formulation and a release rate of 0.5-24 hours. Claim 16 claims the outer layer dissolves within 10 minutes.

Instant application and US '901 are obvious modifications of each other. US '901 is directed to the broader composition (genus) and the instant application recites a species of drugs. Thus, the instant application anticipates US '901.

Copending applicant claims a pharmaceutical composition and a process of making the composition. The composition is in unit dosage form for both intraoral and oral administration to a patient, said unit dosage form configured to be placed intraorally in said patient, which comprises: (a) as a first releasing portion, a molded triturate tablet comprising a therapeutically effective amount of at least one pharmaceutically active ingredient capable of intraoral administration; and (b) as a second releasing portion located around the first portion as a compressed annular tablet, a therapeutically effective amount of at least one pharmaceutically

active ingredient capable of oral administration and which is releasable and orally ingestible by the patient after the molded triturate has disintegrated or has dissolved intraorally. The dependent claims are similar.

Instant application and copending application are obvious modifications of each other. Copending application is directed to the broader composition (genus) and the instant application recites a species of drugs. Thus, the instant application anticipates US '901.

Response to Arguments

Applicant will file a Terminal Disclaimer upon allowance.

Accordingly the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616